REMARKS

Applicant is very appreciative of the Examiner's assistance in furthering prosecution of this application during the interview of August 30, 2007.

1. Amendments to the Claims:

By this amendment, claims 76, 80, 81, 88, and 93 have been amended to clarify the invention claimed. New claim 99 has been added. No new matter is added by the amendments.

Claims 76, 79-83, 85-89, and 93-99 are now pending in the application. Claims 90-92 have been withdrawn.

2. The Rejection of Claim 88 under § 112

In the Office Action, the Examiner rejected claim 88 as being indefinite due to a lack of antecedent basis for the limitation "the collapsible slack portions." Applicant notes that the collapsible slack portions recited are portions of the leaflets, which were previously recited in the claim. By this amendment, the term "collapsible slack portions" has been replaced with the term "leaflets." In view of this amendment, claim 88 is believed to be in compliance with the requirements of § 112.

3. The Rejections of Claims 76, 82, 93, 98 as Anticipated by Letac et al.

In the Office Action, the Examiner rejected claims 76, 82, 93, and 98 as anticipated by Letac et al. (EP 850607). By this amendment, claims 76 and 93 (from which claims 8 and 98 depend, respectively) have been amended to clarify that the valve portion outlet end is upstream of the stent outlet end when the valve portion is in an open configuration. This is in contrast to Letac et al., all embodiments of which include a valve portion that when open is substantially longer than the relatively short stent portion, with the valve portion outlet end extending out of the stent portion. See, for example, FIGS. 4b, 6a-6c, 8a, 9a, 10a, 11a, 13l, and 15f of Letac et al., which depict various embodiments in the open configuration. FIG. 4b is representative and is reproduced below:

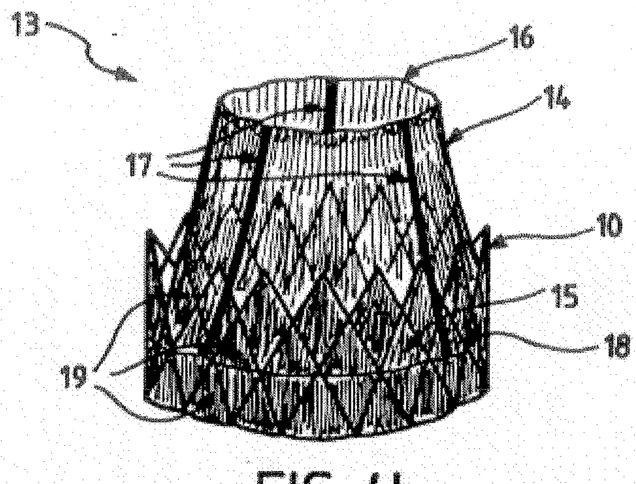


FIG_4b

Letac et al. thus teaches a relatively short stent and relatively long valve structure, in contrast to claims 76 and 93 as amended. In view of the above, it is believed that claims 76 and 93 as amended, as well as claims 82 and 98 which depend therefrom, are allowable over Letac et al.

4. The Obviousness Rejection Over Park et al.

The Examiner rejected claims 76, 79-81, 83, 85, 86, 88, and 93-98 as being obvious over Park et al. (EP 01264582). The claims as amended are believed allowable over Park et al., as discussed below.

In the obviousness rejection over Park et al., the Office stated that it would have been an obvious expedient to modify the prosthesis of Park et al. with a reversal of the valve structure. The Office cited MPEP 2144.04 in support of the position that a mere reversal of essential working parts does not constitute an improved invention. However, Applicant submits that MPEP 2144.04 does not provide a blanket rule that a reversal of working parts is inherently non-patentable. MPEP 2144.04 in fact specifically states, "If the applicant has demonstrated the criticality of a specific limitation, it would be inappropriate to rely solely on case law as the rationale to support an obviousness rejection." MPEP 2144.04, first paragraph. In the current application, Applicant has clearly demonstrated the criticality of the specific limitation that the one-way valve is mounted such that fluid flows from the stent inlet portion (with wider diameter) to the stent outlet portion (with narrower diameter). Moreover, the device of the current application operates in quite a different fashion than the device of Park et al., and the claims are believed to be non-obvious. Accordingly, under the standards set forth in MPEP 2144.04 the claims are not obvious.

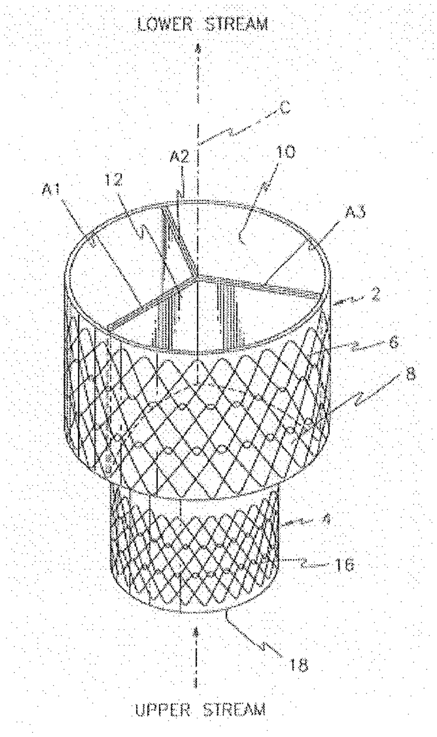
MPEP 2144.04 further states that the Examiner may use the rationale from a court decision "if the facts in a prior legal decision are sufficiently similar to those in an application under examination." Id. [emphasis added]. However, the current facts are not similar to, and are actually quite different from, the facts of the prior legal decision listed in MPEP 2144.04. The court decision cited in MPEP 2144.04 that addresses reversal of elements is In re Gazda, 219 F.2d 449, 104 USPQ 400 (CCPA 1955), which involved a clock secured to a steering wheel and a clock-winding gear secured to the stationary steering column. The prior art had disclosed a clock secured to the stationary steering column (instead of to the steering wheel), with the clock-winding gear secured to the steering wheel. The court held that the mere reversal of the clock and clock-winding gear was obvious. It is notable that the clock in In re Gazda was merely in a slightly different position than the prior art clock, but still functioned in an essentially identical fashion to the prior art clock, i.e., provided the same time, faced the same direction, obtained winding from the rotational movement of the steering wheel, etc. This is in stark contrast to the current application, in which the different position of the one-way valve provides a valve having entirely different operational characteristics.

A case having facts highly similar to those of the current application is In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (CAFC 1984), which involved a blood filter assembly having inlet and outlet portions at the bottom of the filter assembly. The claims of In re Gordon had been initially rejected as obvious as being a mere reversal of a prior art device having inlet and outlet portions at the top (as opposed to the bottom) of the assembly. The appeals court stated that the relevant question was "whether it would have been obvious from a fair reading of the prior art reference as a whole to turn the [prior art] apparatus upside down." In re Gordon, 733 F.2d at 902, 221 USPQ at 1127. The court held that the prior art reference failed to render the claimed "upside-down" invention obvious.

The court in In re Gordon also noted that if the prior art reference were turned upside down, it would be rendered inoperable for its intended purpose, and therefore the prior art reference actually taught away from the proposed modification. Id., citing In re Schulpen, 390 F.2d 1009, 1013, 157 USPQ 52m 55 (CCPA 1968) ("Rather than being made obvious by the [prior art] reference, such modification would run counter to its teaching by rendering the [prior art] apparatus inoperative to produce the disclosed tire patches [i.e., inoperative to perform its intended function]." Id. [comments added]. Accordingly, both the CAFC and the earlier CCPA, in 1984 and 1968, respectively, recognized that a reference teaches away from a modification when the proposed modification would render the reference's device inoperable for its intended purpose.

It is well established that "a prima facie case of obviousness can be rebutted if the applicant . . . can show 'that the art in any material respect taught away' from the claimed invention. In re Geisler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (CAFC 1997) (quoting In re Malagari, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974). In KSR International the Supreme Court recognized the ongoing validity of the "teaching away" factor in assessing obviousness (although the Court found that under the facts of KSR there was no teaching away). KSR International Co. v. Teleflex, Inc., 82 USPQ2d 1385, 1399 (2007).

Park et al. provides a support stent with two sections, with a valve assembly positioned in the first section, but with the second section upstream of the valve inlet end, as can be seen in Figs. 1-4 of Park et al. Referring to Fig. 1 of Park et al., it can be seen that the assembly includes a stent having a first cylindrical body portion (2) and second cylindrical body portion (4), with a valve (12) within the first cylindrical body portion (2). The second cylindrical body portion (4) is upstream of the valve (12) and the first cylindrical body portion (4).



It is not believed that it would be obvious from a fair reading of the Park et al. reference to reverse the valve assembly thereof. The device of Park et al. has a one-way valve and stent, with the downstream (valve-bearing) portion of the device being wider than the upstream portion. The device is described as being configured to permit food and fluids to pass from the narrower portion through the wider portion, while simultaneously preventing food and fluid from passing back from the wider portion into the narrower portion. By having the valve-bearing outlet portion wider than the inlet portion, the "widening" (as opposed to narrowing) stent structure of Park et al. appears to reduce the chances of food or other particles from becoming lodged in the mid-section of the structure, while the "narrowing" in the opposite direction appears to reduce the chance of backflow through the structure. If the valve of Park et al. were reversed as suggested, there would be a substantial narrowing of the stent passage downstream of the valve. Such a rapid narrowing of the passage, particularly when positioned just downstream of a valve intended to permit the passage of materials such as food, does not appear conducive to the easy passage of such particles. Accordingly, Park et al. is believed to teach away from the proposed modification.

A person of ordinary skill in the art would not have been motivated toward the proposed modification to Park et al., particularly in view of Park et al. teaching away from the proposed modification. The upstream positioning of the smaller stent portion with respect to the valve inlet end taught by Park et al. is directly contrary to claims 76, 79-81, 83, 85, 86, 88, and 93-98 (including amendments thereto), all of which include the limitation (either directly or through dependence) that the second (i.e., smaller) portion of the stent is downstream of the valve inlet end with respect to fluid flowing through the one-way valve. Accordingly, claims 76, 79-81, 83, 85, 86, 88, and 93-98 as amended are believed allowable over Park et al.

5. The Obviousness Rejection over Park et al. and Zakai et al.

Claims 82, 87, and 89 were rejected as being obvious over Park et al. in view of Zakai et al., with Zakai et al. cited as teaching the use of pericardial tissue for the valve and metal for the stent. However, Zkai et al. provides no teaching or motivation toward an assembly wherein a one-way valve is positioned in a relatively wide upstream stent portion secured to a narrower downstream portion. Claims 82, 87, and 80 depend from claims that recite a one-way valve positioned in a wide stent portion that is upstream of a narrower stent portion. As set forth above, Park et al. teaches away from such a device. Accordingly, claims 82, 87, and 89 are believed allowable over the proposed combination of Park et al. and Zakai et al.

6. Additional Distinguishing Elements in the Claims:

In addition to the above-cited distinctions between the claims and the cited art, by this amendment additional limitations have been added, either via amendment to prior claims or by adding new claims. These additional limitations are believed to further distinguish the claims from the cited art.

Independent claim 76 has been amended to include the further limitation that the stent support structure is generally continuous and free of sharp longitudinal angles from inlet portion to outlet portion. This is in contrast to Park et al., which describes a midsection (20) having different material structure (resins, etc.) and characteristics (non-elastic, etc.) from the adjacent downstream stent portion (2) and upstream stent portion (4), as well as having relatively sharp longitudinal angles (when viewed from the side as in Figs. 2 and 4) between adjacent sections. Park et al., paras. 0046 and 0047, Figs. 2 and 4. Accordingly, claim 76 as amended (and its dependent claims 79-82 and 99) are allowable over the cited art.

Dependent claim 81 has been amended to recite the stent portion adjacent to the valve assembly inlet has a diameter larger than the valve assembly inlet diameter. This is in contrast to the cited art, which all include valve structures having inlet diameters essentially the same size as the valve inlet diameter. Therefore claim 81 as amended is allowable over the art of record.

Independent claim 93 has been amended, and new claim 99 (depending from claim 76) has been added, to include the further limitation of relatively rigid longitudinal beams extending lengthwise along the stent and connecting the stent inlet portion to the stent outlet portion. Such a feature is not taught by Park et al., and Park et al. in fact teaches away from such a feature. More specifically, Park et al. teaches inclusion of an intermediate section that is formed of non-elastic resin in order to isolate the downstream portion from the upstream portion, and more specifically to prevent deformation forces from the narrower upstream portion from being transmitted to the wider downstream (valve-bearing) portion. Park et al., FIG. 4, paras. 0046,

0047. The inclusion of the longitudinal and generally rigid beams of claims 93 and 99 is contrary to this purpose of Park et al. because the configuration of the generally rigid beams will inherently transmit deformation forces from the inlet portion to the outlet portion, and vice-versa. Accordingly, claim 93 as amended (and its dependent claims 94-98) and new claim 99 are allowable over the cited art.

7. Fees for this Amendment

The addition of claim 99 puts the total number of claims at 21, so that an additional fee of $50.00 for the additional (dependent) claim is now due. No other fees are believed necessary. The Commissioner is hereby authorized to charge the extra claim fee of $50.00, as well as any other fee required in connection with this Amendment, to Deposit Account No. 50-1225 (Docket No. PVI-5790).

Conclusion

Should the Examiner have any questions, the Examiner is encouraged to contact the attorney of record at the telephone number shown below.

Respectfully submitted,

Date: 10/9/2007

Richard B. Cates, Registration No. 36,100
c/o David L. Hauser, Registration No. 42,643
EDWARDS LIFESCIENCES LLC
One Edwards Way
Legal Department
Irvine, California 92614
Telephone: (949) 250-6878
Facsimile: (949) 250-6850